

REMARKS

This amendment is submitted with a Request for Continued Examination pursuant to 37 C.F.R. 1.114. The amendment and remarks address the issues raised in the Office Action dated November 15, 2006.

After entry of the present amendments, claims 2, 7-26, 29-34, 36, 38, 39, 44-56, 59, 60, and 105-121 will be pending. Claims 1, 3-6, 27, 28, 35, 37, 40-43, 57, 58, and 61-104 have been cancelled. The Applicants reserve the right to present the subject matter of the cancelled claims in one or more continuing applications. Claims 2, 7, 10-15, 17-26, 29-34, 36, 38, 39, 44, 48-55, 56, and 59 have been amended to correct typographical errors and to even more particularly describe the recited inventions. Claims 106-121 have been added. The specification has also been amended to correct a typographical error. No new matter has been added.

Rejections under 35 U.S.C. § 112

Claims 1, 2, 27-29, 57, 59, and 105 stand rejected under 35 U.S.C. § 112 as allegedly indefinite as to the term “low molecular weight” because “[i]t is not clear if the actual definition encompasses only the broadest embodiment, or if the term is limited to one of the ‘preferred’ embodiments.” Office Action at 3. The Applicants traverse and request withdrawal of the rejection.

As set forth in MPEP § 2173.05(a), “[d]uring patent examination, the pending claims must be given the *broadest reasonable interpretation* consistent with the specification.” (emphasis added). The definition of “low molecular weight” is clearly set forth in the specification at paragraph 64 with the broadest reasonable interpretation of that term being “having a weight average molecular weight ranging from about 3000 to about 10,000.” One of ordinary skill in the art would be able to “interpret the metes and bounds of the claims so as to understand how to avoid infringement.” MPEP § 2173.02. Thus, the claims are not indefinite and the Applicants request withdrawal of the rejection.

Claims 1-60 and 105 stand rejected under 35 U.S.C. § 112 as allegedly indefinite as to the term “amount effective to plasticize” because “[i]t is not clear how much the polymer

must be ‘plasticized’ in order for the amount to be ‘effective.’” Office Action at 3. The Applicants traverse and request withdrawal of the rejection.

“The proper test” for indefiniteness “is whether or not one skilled in the art could determine specific values for the amount based on the disclosure.” MPEP 2173.05(c)(III). Moreover, a claim that states the function that is to be achieved is not indefinite. *See id.* The present claims describe, *inter alia*, compositions having a solvent “in an amount effective to plasticize the polymer and form a gel therewith.” Moreover, the specification describes that compositions of the present invention can be injectable, with varying viscosities. *See, e.g.*, paragraphs 75, 112, 113. The specification also describes compositions of the present invention administered as a leave-behind product. *See, e.g.*, paragraph 118. One of skill in the art, thus armed with the disclosure of the specification, would understand how much the polymer must be plasticized in order for the amount to be effective. The Applicants respectfully request withdrawal of the rejection.

Claims 4, 5, 8, and 41 stand rejected under 35 U.S.C. § 112 as allegedly indefinite as to the term “lower alkylene” because “[i]t is not clear if the actual definition encompasses only the broadest embodiment, or if the term is limited to one of the ‘preferred’ embodiments.” Office Action at 4. As set forth above, “[d]uring patent examination, the pending claims must be given the *broadest reasonable interpretation* consistent with the specification.” (emphasis added). The definition of “lower alkylene” is clearly set forth in the specification at paragraph 68 with the broadest reasonable interpretation of that term being “an alkyl group of 1 to 6 carbon atoms.” One of ordinary skill in the art would, therefore, be able to “interpret the metes and bounds of the claims so as to understand how to avoid infringement.” MPEP § 2173.02. Applicants respectfully request withdrawal of the rejection.

Claims 15, 17, and 35 stand rejected under 35 U.S.C. § 112 as allegedly indefinite as to the phrase “lactic acid-based polymer” because the “portions of the specification cited in Applicants’ reply do not provide a definition of this term” and that the “metes and bounds are not clear to the artisan.” Office Action at 4. The Applicants traverse and request withdrawal of the rejection. Paragraph 80 of the specification recites, “Presently preferred polymers are polylactides, that is, a lactic acid-based polymer that can be based solely on lactic acid or can be a copolymer based on lactic acid and glycolic acid which may include small amounts of

other comonomers that do not substantially affect the advantageous results which can be achieved in accordance with the present invention.” Paragraph 80 further defines the term “lactic acid.” Paragraph 81 describes the molecular weight ranges of the “lactic acid-based polymer” and provides references to United States patents for the preparation of such materials. Paragraphs 81, 82, and 83 reference no fewer than 16 exemplary commercially available “lactic acid-based polymers” useful with the present invention. Based on the detailed definitions and disclosure provided in the specification, one of skill in the art would most certainly understand the metes and bounds of the phrase “lactic acid-based polymer.” The Applicants respectfully request withdrawal of the rejection.

Claims 21, 22, 51, and 52 stand rejected under 35 U.S.C. § 112 as allegedly indefinite as to the phrase “analog, derivative, and fragments thereof.” Although the Applicants do not necessarily concur and continue to maintain that it would be clear to one of skill in the art whether a particular substance is an analog, derivative, and/or fragment, the claims have been amended to further the prosecution of the present application. The rejection is thus moot.

Rejections under 35 U.S.C. § 102

Claims 1-24, 27-32, 34-47, 49-54, 57-60, and 105 stand rejected under 35 U.S.C. §§ 102(a) and 102(e) as allegedly being anticipated by WO 02/3185 (“Dunn”). The Applicants disagree and request withdrawal of the rejection.

For a reference to be anticipatory, it must describe “all elements of [the] claimed invention arranged as in that claim.” *Carella v. Starlight Archery*, 804 F.2d 135, 138 (Fed. Cir. 1986); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1267 (Fed. Cir. 1991). Importantly, for a rejection to be proper under 35 U.S.C. § 102, the reference must “clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *In re Arkley*, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972) (emphasis in original).

The present invention requires a solvent “having miscibility in water of less than or equal to 7% at 25 °C, in an amount effective to plasticize the polymer and form a gel therewith.” These limitations are not found in Dunn. Firstly, Dunn teaches that the polymer is *dissolved* in solvent. Dunn further instructs that the polymer is dissolved in a solvent to

form a flowable composition. See, e.g., Dunn, page 11, line 30–page 12, line 1; page 14, lines 30–31; claim 1. Nowhere in the specification is the formation of a *gel* described, as required by the claims of the present invention.

In addition, while the present invention requires a solvent “having miscibility in water of less than or equal to 7% at 25 °C,” Dunn, in contrast, teaches that the solvent *must be miscible in aqueous medium*. Dunn at page 14, lines 2–4. Dunn instructs that “[s]uitable biocompatible organic solvents are disclosed, e.g., in Aldrich Handbook of Fine Chemicals and Laboratory Equipment,” a 2400 page catalog of reagents and chemicals. Dunn at page 14, lines 5–6. Dunn also instructs that suitable biocompatible organic solvents are disclosed in 20 U.S. patents, as well as in the references cited in those patents. Dunn at page 14, lines 6–10. Rather than provide guidance as to what solvents fall within the Dunn definition of “miscible in aqueous medium,” Dunn teaches that any and all solvents are appropriate.

Dunn then proceeds to list no fewer than 37 solvents as preferred embodiments, all having varying physical properties. Dunn at page 14, lines 11–21. Two of the solvents described in the present invention are listed among these 37 solvents. Dunn further describes 8 solvents as being particularly preferred, with NMP (N-methyl-2-pyrrolidone) being the most preferred solvent. Therefore, notwithstanding that Dunn does not describe the formation of a gel as required by the claims of the present invention, one of skill in the art would only arrive at the claimed invention by performing the “picking and choosing” expressly prohibited by *In re Arkley*. The claimed invention is not “identically disclosed or described in the prior art;” therefore, the rejection under 35 U.S.C. § 102 is inappropriate and the Applicants respectfully request that it be withdrawn. See *In re Arkley*, 172 USPQ at 526.

Furthermore, the present invention, as currently amended, requires that the composition deliver the beneficial agent in a controlled manner over a duration less than about seven days. Dunn does not describe any composition that delivers a beneficial agent in a controlled manner over a duration of less than about seven days. Thus, the claimed invention is not identically disclosed or described in Dunn and the Applicants submit this is another basis for withdrawal of the rejection under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 103

Claim 33 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Dunn. The Applicants submit that there is no disclosure or suggestion to arrive at a composition comprising the gel, miscibility, and delivery rate properties defined in Applicants' claims, including claim 33.

For example, not only does Dunn fail to expressly teach or describe solvents "having miscibility in water of less than or equal to 7% at 25 °C" (*see supra*), one of skill in the art would not be motivated to modify the teachings of Dunn to produce the claimed invention requiring such solvents. Firstly, Dunn teaches that solvents must be *miscible in aqueous medium*, in contrast to the claimed invention requiring a specific miscibility of less than or equal to 7% at 25 °C. Moreover, Dunn provides no guidance as to what solvents would fall within the definition of being "miscible in aqueous medium." Rather, Dunn directs one of skill in the art to *every* commercially available solvent. *See supra*.

And while Dunn sets forth a list of at least 37 "preferred" solvents, the solubility properties of these preferred solvents vary, ranging from those being completely miscible in water to those having no miscibility in water. Dunn at page 14, lines 11-21. The more preferred list of 8 solvents are "polar aprotic solvents" that are generally very soluble in water. Dunn at page 14, lines 22-29. Indeed, the most preferred solvent, in fact the only solvent *expressly* used in Dunn, is NMP, a solvent that is very miscible in water. Dunn at page 14, line 29; pages 21-23. Therefore, one of skill in the art, after reading the disclosure of Dunn, would not be motivated to select solvents "having miscibility in water of less than or equal to 7% at 25 °C."

As already explained in connection with the rejection under 35 U.S.C. § 102, Dunn also fails to disclose gels. Given the complete lack of disclosure regarding gels, Dunn does not provide any motivation or suggestion to arrive at Applicants' claimed invention.

Additionally, Dunn does not disclose or suggest a composition that delivers a beneficial agent in a controlled manner over a duration of less than about seven days, as set forth in the currently amended claims. Aside from cursory statements that the compositions described in Dunn may be "suitable for use as a controlled release implant," (Dunn at page 4, lines 1-2) Dunn provides no guidance as to how the compositions described therein should be

modified to produce compositions according to the claimed invention that deliver beneficial agent in a controlled manner over a duration less than about seven days.

In view of the above, Dunn does not teach all the limitations of the claimed invention and fails to provide motivation or suggestion to one of ordinary skill in the art to modify the reference to produce the claimed invention. Therefore, a *prima facie* case of obviousness has not been made and the Applicants respectfully request that the rejection of claim 33 under 35 U.S.C. § 103 be withdrawn.

Claims 25, 26, 55, and 56 stand rejected as allegedly obvious over Dunn in view of WO 00/74650 (the 650 reference). As described above, Dunn, the primary reference, fails to disclose or suggest a solvent “having miscibility in water of less than or equal to 7% at 25 °C, in an amount effective to plasticize the polymer and form a gel therewith.” In addition, neither Dunn nor the 650 reference describes a composition that delivers beneficial agent in a controlled manner over a duration of less than about seven days, as presently claimed. Accordingly, both references fail to set forth all the limitations of the claimed invention and fail to provide any motivation or suggestion to one of ordinary skill in the art to modify the references to produce the claimed invention; therefore, a *prima facie* case of obviousness has not been established and the Applicants request withdrawal of the rejection of claims 25, 26, 55, and 56 under 35 U.S.C. § 103.

Nonstatutory Judicially Created Obviousness-Type Double Patenting Rejections

The Applicants acknowledge the provisional nonstatutory judicially created doctrine of obviousness-type double patenting rejections. Upon an indication of the allowability of the claims of the present application, the Applicants will consider whether the filing of terminal disclaimers would be appropriate.

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**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

Conclusion

The Applicants respectfully submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

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